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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,682	03/17/2004	Akira Asakura	13735 US1 (C038435/010970)	9826
7590 07/12/2006				
Stephen M. Haracz, Esq. BRYAN CAVE LLP 1290 Avenue of the Americas New York, NY 10104-3300			EXAMINER WALICKA, MALGORZATA A	
			ART UNIT 1652	PAPER NUMBER

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/802,682

Applicant(s)

ASAKURA ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 9, 20-22, 25 and 28-31 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 is/are allowed.
- 6) ☒ Claim(s) 1-3, 20-22, 25 and 28-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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The examiner acknowledges the Amendment filed April 27, 2006. Claims 1, 2, 9, 25, 30 and 31 have been amended. Claims 4-8, 10-19, 23-24 and 26-27 were previously canceled. Claims 1-3, 9, 20-22, 25, 28-31 are pending and are the subject of this Office Action.

## **DETAILED ACTION**

### **1. Rejections**

#### ***1.1. 35 U.S.C. 101***

Rejection of claim 1-3, 9, 29-31 made in the Office action of Oct. 20, 2005 (previous action) is withdrawn, because the claims have been amended.

#### ***1.2. 35 U.S.C. 112 second paragraph***

Claims 1, 2, 3, 20-22, 25-26 and 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the phrase "hybridizes under standard conditions" which being indefinite, renders the claim indefinite. There are many sets of hybridization conditions in the prior art that are used for identifying DNA molecules by hybridization, and the choice of a particular set depends on the experimenter and the experimental problem at hand. Different hybridization conditions leads to different selection of DNA molecules. The claims do not explicitly state the conditions which Applicants call "standard". Applicants in their REMARKS refer the examiner to the standard hybridization conditions which are

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described, "e.g. by Sambrook et al. 'Molecular Cloning' second edition", specification page 16. Applicants refer to Sambrook in an exemplary way and do not quote any page presenting the conditions. It is unknown what conditions considered "standard" in the art are included and/or excluded from the scope of the claims.

### **1.3. 35 U.S.C. 112 first paragraph**

#### **Scope of enablement**

Claims 1-3, 20-22, 25, 28, 30-31 were rejected in the previous action because the specification, while being enabling for the alcohol and aldehyde dehydrogenases of SEQ ID NO: 5, 6, 7, and 8, does not reasonably provide enablement for any amino acid sequence comprising a sequence that has at least 80% identity to SEQ ID NO: 8. This ground of rejection is overcome by the current amendment. However, because the disclosure does not teach the hybridization conditions to be used in selection of DNA molecules of invention, claims 1-3, 20-22, 25, 28, 30-31 as amended are not enabled and thus rejected.

#### **Response to Applicants' arguments**

In their REMARKS of April 27, 2006, page 13, under Table 7, Applicants emphasize that the degree of homology between the enzymes disclosed and identified as SEQ ID NO: 5, 6, 7, and 8 is at least 80%, and any known alcohol dehydrogenase activity was in the range of 26 to 31%. From this fact Applicants drawn the conclusion "Thus, the data in Table 7 [quoting homologies of SEQ ID NO:5, 6, 7, and 8] clearly provides evidence that the Applicants enabled the full scope of the amended claims, by

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unambiguously identifying enzymes having highly homologous polypeptide sequences and sharing a common function-AADH activity. Accordingly, it is respectfully submitted that undue experimentation would not be required to carry out the currently claimed invention."

Applicants' argument has been fully considered but is found not persuasive, because it is an argument pertaining to the question of existence of prior art, and not the question of enablement. Applicants are reminded that the instant application is a divisional of US application 09/470,667 in which claims directed to DNA molecules were prosecuted, and US patent No. 6,730, 503 was issued because of lack of prior art, i.e., rejection under 35 USC 102. Lack of a prior art in the instant application does not automatically enable the claims.

In addition, claim 2 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the plasmid comprising genes encoding SEQ ID NO: 5 and SEQ ID NO: 8 (plasmids pSSAB201 and pSSBA201), does not reasonably provide enablement for an enzyme that comprises a combination of at least two amino acids sequences each of said sequences being selected from the group of SEQ ID NO: 8 and SEQ ID NO: 5 and amino acid sequences encoded by DNA sequences hybridizing under standard conditions with DNA molecules according to SEQ ID NO:4 or 1. The reasons for this rejection are almost the same as explained in the previous actions, i.e., without a further guidance on the part of Applicants related to the structure of chimeric enzymes, one skilled in the art is forced to construct numerous

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combination of disclosed sequences and/or sequences that are hybridizing to SEQ ID NO:1 or SEQ ID NO:4 under indefinite conditions, wherein the sequences to be constructed, due to the open language of the claims "including a combination of at least two amino acid sequences" comprise does encoding linking polypeptide sequences or amino acids not taught by the disclosure, as well as flanking sequences. Furthermore, the order of the structural elements of chimeric proteins is important for the activity but not taught. The constructs are to be expressed and expressed chimeric proteins, must be tested for their enzymatic activity. All the manipulation and test have a low probability of success. In summary, without a further guidance on the part of Applicants in regards of structure of the claimed polypeptides, experimentation left to those in the art is improperly extensive and undue.

#### Response to Applicants' traverse

On page 14 of their REMARKS Applicants refer the examiner to Examples 14, 15 and Figures 2, 3, 4, 7, and 8 as illustrating currently claimed chimeric nucleic acid molecules.

Applicants' arguments are not persuasive. As explained in details in the first Office action on merits mailed Dec. 1, 2004, the structure of the claimed hybrid enzymes and encoding DNA molecules is not taught, although all of them have the same function. The figures are schematic and for that reason do not identify the details of structure, i.e., sequences, of claimed hybrid molecules. What Applicants expect from one skilled in the art is actually "a result that one might achieve if one made that

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invention"; see *Eli Lilly*, 119 F.3d at 1568. 43 USPQ2d at 1406 as quoted in MPEP page 2100-173 paragraph (2).

### **3. Conclusion**

Claim 9 is allowed. Applicant is reminded that allowable subject matter was indicated by the examiner in the First Office Action on merits on Dec. 1, 2004.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (571) 272-0944. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m. If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (571) 272-1600. The fax phone number for this Group is (703) 305-3014. Any inquiry of a


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general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 872-9306.

Malgorzata A. Walicka, Ph.D.

Patent Examiner

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REBECCA E. PROUTY  
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